510(K) SUMMARY

SEP 24 2010

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. **Submitter's Identification:**

Christopher Wybo
Director of Engineering and Regulatory
Innovative Surgical Solutions, LLC
1002 Hoffman Ave.
Royal Oak, MI 48067
Tel: (248) 416-0740
Fax: (800) 683-8144

Date Summary Prepared: September 24, 2010

2. **Name of the Device:**

Trade or Proprietary Name:	NeuralMAS™
Classification Name:	Surgical Nerve Stimulator/Locator
Device Class:	Class II
Classification:	21 CFR §874.1820
Product Code:	ETN

3. **Common or Usual Name:**

Nerve Mapping and Avoidance System, Intraoperative Mechanomyographic (MMG) Monitor/Stimulator, Nerve Locator/Stimulator

4. **Predicate Device Information:**

The subject device NeuralMAS™ is substantially equivalent to one or more of the following predicate devices:

K031510	NIM-Spine, Medtronic Xomed, Jacksonville, Florida
K072736	Rhythmlink, Columbia, South Carolina
K062996	Axon Systems, Hauppauge, New York
K000722	UniPlex Nanoline Cannula, Pajunk GMBH, Geisingen, Germany

5. Device Description:

The NeuralMAS™ system is a multichannel intraoperative monitor for use during surgeries in which a motor nerve is at risk. The NeuralMAS™ system records mechanomyographic (MMG) signals from muscles innervated by the affected nerve, which may originate from operator applied electrical stimulus or from direct or indirect mechanical stimulus occurring during the course of surgery. The monitor will assist early nerve identification by providing the surgeon with a tool to help locate and identify the particular nerve at risk to minimize trauma by alerting the surgeon when a particular nerve has been activated.

The NeuralMAS™ system consists of a reusable Patient Module, a Control Unit comprised of a touch-screen PC and an assortment of disposable conductive probes, stimulators, sensors, electrodes and electrode leads.

6. Intended Use:

This device is intended for use in surgical procedures to assist in locating and mapping motor nerves through the use of mechanomyographic (MMG) signals and electrical stimulus of nerves. This device is indicated for locating and identifying spinal nerve roots and peripheral motor nerves originating from spinal levels C3-T1 and L2-S2.

7. Comparison to Predicate Devices:

The subject device has indications for use which are substantially equivalent to the predicate device, is composed of the same or equivalent materials as one or more commercially marketed devices, has the same or equivalent design features as the predicate device, is substantially equivalent in its method of use, and has functional characteristics which are the same or equivalent to those of one or more of the predicate devices. Due to the equivalency of indications for use, materials of composition, design features, method of use, and functional characteristics, the device raises no new safety or effectiveness issues.

Table 1: Overview & Indications

Subject Device: ISS NeuralMAS	Predicate Device: Medtronic NIM-Spine #K031510
System Overview Uses low level electrical current to stimulate nerves sufficient to produce a detectable mechanical signal in contracting muscle using skin-surface mounted mechanomyographic (MMG) sensors.	**System Overview** Uses electrical current varying between low and high levels to induce current flow in stimulated nerves sufficient to produce a detectable electrical signal in contracting muscle using EMG needle electrodes placed in the muscle.

Table 2: Physical Attributes

Attribute	ISS NeuralMAS	Medtronic NIM-Spine #K031510
Control Module: PC/Display		
Type:	Touchscreen	Touchscreen
Number of Channels:	10	8
Channel Enable/Disable Controls:	Touchscreen controlled	Dedicated function touchpads for independent channel enable/disable
Event Threshold Control and Display:	Touchscreen controlled	Adjustable graduated touchbar with voltage threshold display
Stimulator		
Type Constant:	Electrical Current (mA)	Electrical Current (mA)
Range:	1-15 mA	1-200 mA, max 540V compliant
Control:	Digitally controlled	Digitally controlled
Waveform:	Monophasic, square pulse	Monophasic, square pulse
Pulse Duration:	100µs	50, 100, 150, 200 or 250µs

Rate:	2Hz	Switch selectable: 1, 5, or 10Hz
Stimulus Probe:	Monopolar	Monopolar or bipolar
Activation:	Touch screen or hand switch	Two step touch screen or hand switch
Monitoring Sensor		
Function:	Mechanomyographic (MMG)	Electromyographic (EMG)
Type:	Electromechanical	Subdermal needle electrodes
Attachment Site:	Skin surface	Subdermal
Attachment Mode:	Adhesive	Subdermal needle

8. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

A comparative performance evaluation was conducted in the sheep to assess statistical agreement between the subject device and the predicate. Results for positive, negative, and overall percent agreement have established that 1) the principle functions of the NeuralMAS™ system are effective, such that spinal nerve status and location may be ascertained and monitored, and 2) the data acquired by the subject device during simulated surgical use in the animal model correlate well with those acquired simultaneously by a predicate device.

9. **Discussion of Clinical Tests Performed:**

Not Applicable

10. **Conclusions:**

The conclusions drawn from our non-clinical testing (to include our animal testing) of the subject device demonstrates that the subject device is as safe, as effective and performs as well as the legally marketed predicate device. The subject device is substantially equivalent in function to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Innovative Surgical Solutions, LLC
c/o Ms. Susan Goldstein-Falk
MDI Consultants, Inc.
55 Northern Boulevard, Suite 200
Great Neck, New York 10021

SEP 24 2010

Re: K100992
Trade/Device Name: NeuralMAS
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: ETN
Dated: August 27, 2010
Received: September 1, 2010

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K100992

Indications for Use

510(k) Number (if known): K100992

SEP 24 2010

Device Name: NeuralMAS

Indications For Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

Prescription Use X
(Per 21 CFR 801.109)

510(k) Number K100992